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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/700,625 02/01/01 SAWYNOK

J DALH01290-1

EXAMINER

HM12/1010

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WARE, T

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/700,625

Applicant(s)

SAWYNOK ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-53 and 63-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-53, 63-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt of preliminary amendment, change of address, associate power of attorney, and request for refund all filed 5-1-01 is acknowledged. Claims 1-25 and 54-62 have been canceled as requested. Claims 26-53 and 63-71 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 63-71 provide for the use of a tricyclic antidepressant, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 63-71 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 26-29, 31-36, 42-46, 48-50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bernstein (4,395,420; hereafter '420).

'420 discloses topical tricyclic antidepressant compositions for treating pruritis.

The compositions comprise for example doxepin or amitriptyline and are in the form of creams, ointments, and lotions and comprise ethanol or white petrolatum (column 2, claims).

7. Claims 26-29, 31-36, 42-46, 48-50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Frome (WO 97/10815; hereafter '815).

'815 discloses topical tricyclic antidepressant compositions comprising water and lecithin (page 11-12, 15, 17; claims).

8. Claims 26-29, 31-47, 49-53 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kitchel et al (5,486,362; hereafter '362).

'362 discloses topical controlled release microsphere compositions comprising tricyclic antidepressants. The compositions of '362 are administered by local injection (claims).

9. Claims 26-51 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Smith et al (5,922,341; hereafter '341).

'341 discloses topical antidepressant compositions for treatment of premature ejaculation (abstract; column 4, line 19-column 5, line 25; examples; claims).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 26-36, 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (4,395,420; hereafter '420) or Frome (WO 97/10815; hereafter '815)

'420 teaches topical tricyclic antidepressant compositions for treating pruritis. The compositions comprise for example doxepin or amitriptyline and are in the form of creams, ointments, and lotions and comprise ethanol or white petrolatum (column 2, claims).

'815 teaches topical tricyclic antidepressant compositions comprising water and lecithin (page 11-12, 15, 17; claims).

Manipulation of the amounts of ingredients would have been obvious to one skilled in the art at the time of the invention in an effort to increase or decrease the amount of effect. Also, the instant claims recite compounds that differ as adjacent lower homologs. The claimed invention would have been obvious to the skilled artisan because close structural similarity of the reference compound suggests the claimed

compound. One skilled in the art would expect the two compounds to have similar properties.

12. Claims 26-36, 42-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitchel et al (5,486,362; hereafter '362).

'362 teaches topical controlled release microsphere compositions comprising tricyclic antidepressants. The compositions of '362 are administered by local injection (claims).

Manipulation of the amounts of ingredients would have been obvious to one skilled in the art at the time of the invention in an effort to increase or decrease the amount of effect. Also, the instant claims recite compounds that differ as adjacent lower homologs. The claimed invention would have been obvious to the skilled artisan because close structural similarity of the reference compound suggests the claimed compound. One skilled in the art would expect the two compounds to have similar properties.

13. Claims 26-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (5,922,341; hereafter '341).

'341 teaches topical antidepressant compositions for treatment of premature ejaculation (abstract; column 4, line 19-column 5, line 25; examples; claims).

Manipulation of the amounts of ingredients would have been obvious to one skilled in the art at the time of the invention in an effort to increase or decrease the amount of effect.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


THURMAN K. PAGE
SUPERVISOR PATENT EXAMINER
TECHNOLOGY CENTER 1600

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October 1, 2001